510(k) SUMMARY

The 510(k) Summary is submitted as required by section 807.92(a)

SPONSOR:

Volcano Corporation
2870 Kilgore Road.
Rancho Cordova, CA 95670

CONTACT/SUBMITTER:

Marcus Garcia
Regulatory Affairs Specialist
Volcano Corporation
1 Fortune Drive
Billerica, MA 01821
Tel: (978) 439-3312
Fax: (978) 262-0035

SEP 2 7 2013

DATE OF SUBMISSION: August 23, 2013

DEVICE: Volcano PreView® Forward-Looking IVUS System

Trade Name: Volcano PreView® Forward-Looking IVUS System

Common Name: Ultrasound Catheter/Catheter, Ultrasound, Intravascular; Percutaneous Catheter

Classification: 870.1250 Percutaneous Catheter, II, DQY
870.1200 Diagnostic Intravascular Catheter, II, OBJ

PREDICATE DEVICE: PreView® Forward-Looking IVUS Catheter and Laptop System (K122826)
Volcano s5™/s5i Intravascular Ultrasound Imaging and Pressure System (K123898)

DEVICE DESCRIPTION: The PreView® Forward-Looking IVUS System consists of the PreView® catheter, PIMf, FL.IVUS Software and Volcano s5™ System. The PreView® Catheter is a single use disposable device with a disposable single use motor for rotation of the catheter. The catheter is 135cm in length and connects to a PIM (Patient Interface Module; PIMf) which contains the electronics. The PIMf translates the echo data and sends it to the Volcano s5™ System for display on the system monitor.

INTENDED USE: The PreView® Forward-Looking IVUS System is indicated for use to facilitate the intraluminal placement of

guidewires in the peripheral vasculature prior to further percutaneous intervention and to support guidewires in accessing discrete regions of the peripheral vasculature, to assess vessel morphology, assess the position of the catheter tip within the vessel lumen, and to facilitate placement and exchanges of guidewires and other interventional devices. The PreView® Forward- Looking IVUS System is designed as an adjunct to conventional angiographic procedures to provide a forward-looking image of the vessel lumen and wall structures.

The PreView® Forward-Looking IVUS System is not indicated for use for imaging with the exposed rotating tip inside a stent. This device is not indicated for use in coronary or cerebral vessels.

COMPARISON OF CHARACTERISTICS:

The proposed device is substantially equivalent to currently marketed devices. The devices are ultrasonic pulsed echo imaging systems that consist of catheters, patient interface modules, software and system computers that allow the user to generate images of coronary arteries or peripheral vasculature. They share the same intended use, same design characteristics, and the same fundamental scientific technology.

PERFORMANCE DATA:

Applicable testing was performed as required by the Quality System to evaluate the modifications necessary for the FL.IVUS imaging modality to be compatible with Volcano s5™ System. The following tests were conducted:

- Software Verification and Validation
- Packaging Validation FL.IVUS Modality Option
- Verification of support for FL.IVUS modality operation on the s5™ System
- Electrical Safety Test
- Electromagnetic Compatibility test

Completion of these tests concluded that the PreView® Forward-Looking IVUS System is substantially equivalent to the currently marketed predicate devices.

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Volcano Corporation
Marcus Garcia
1 Fortune Drive
Billerica, MA 01821 US

Re: K132659
Trade/Device Name: Volcano Preview Forward-Looking IVUS System
Regulation Number: 21 CFR 870.1250
Regulation Name: Ultrasound Catheter/Catheter, Ultrasound, Intravascular, Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, OBJ
Dated: August 29, 2013
Received: August 30, 2013

Dear Marcus Garcia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132659

Indications for Use Statement

510(k) Number (if known)

Device Name: Volcano PreView® FL.IVUS System

Indications for Use: The PreView® Forward-Looking IVUS System is indicated for use to facilitate the intraluminal placement of guidewires in the peripheral vasculature prior to further percutaneous intervention and to support guidewires in accessing discrete regions of the peripheral vasculature, to assess vessel morphology, assess the position of the catheter tip within the vessel lumen, and to facilitate placement and exchanges of guidewires and other interventional devices compatible with 0.0 14" guidewire lumens. The Preview® Forward-Looking IVUS System is designed as an adjunct to conventional angiographic procedures to provide a forward-looking image of the vessel lumen and wall structures.

The PreView® Forward-Looking IVUS System is not indicated for use for imaging with the exposed rotating tip inside a stent. This device is not indicated for use in coronary or cerebral vessels.

Prescription Use ___X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.09.27
15:28:02 -04'00'